UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

DONALD J. TRUMP, in his official capacity as President of the United States of America, et al.,

Defendants.

NO.

DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PHD

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
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I, Armand H. Matheny Antommaria, hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I am over 18 years old, of sound mind, and in all respects competent to testify.

2. I have actual knowledge of the matters stated herein.

3. In preparing this declaration, I reviewed Executive Order 14168 of January 20, 2025 "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" and Executive Order 14187 of January 28, 2025 "Protecting Children From Chemical and Surgical Mutilation." In addition to these Executive Orders and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely upon when forming opinions on subjects. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my areas of expertise.

I. OVERVIEW

4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 44 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine,* and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed Executive Orders 14168 and 14187 and submit this declaration to explain my disagreement with and concerns about their conclusions.

5. Executive Order 14168 seeks to end "gender ideology extremism" by recognizing two distinct sexes and excluding references to gender and gender identity. It directs that the definitions of terms like "sex," "male," and "female" given in the Order "govern all Executive interpretation of and application of Federal law and administration policy." Executive Order

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14187 seeks to end the "chemical and surgical mutilation of children" including the use of "puberty blockers." I will refer to puberty blockers as gonadotropin releasing hormone (GnRH) agonists and the use of GnRH analogs, sex hormones, and surgery to treat gender dysphoria collectively as gender-affirming medical care, and the individuals to whom they are prescribed as minors or adolescents. These Orders seek to achieve their goals, in part, by withholding or withdrawing funding and threatening to criminalize that care.

6. There is no sound medical or ethical basis for precluding the use of the terms gender and gender identity or the provision of gender-affirming medical care to adolescents. Executive Order 14168's definitions of sex do not adequately describe many individuals, and gender and gender identity are important aspects of human experience and do not deny the "biological reality of sex." Gender-affirming medical care is evidence-based and the evidence for it is comparable to the evidence for many other treatments in pediatrics. The potential benefits and risks of gender-affirming medical care are comparable to those of other forms of medical treatment—treatment for which parents or legal guardians are capable of providing informed consent and minor adolescents are capable of providing assent. Executive Order 14187 would preclude healthcare providers from providing their patients with needed, evidence-based care.

7. There is no sound medical or ethical basis for singling out gender-affirming medical care for negative treatment. Treatment of gender dysphoria is not experimental, is supported by evidence of safety and efficacy, and is consistent with generally accepted professional medical standards. As a result, Executive Order 14187 excludes such care from coverage in a manner inconsistent with other medical coverage decisions. Furthermore, it pits one group of patients against another by threatening to withhold not only funding for gender-affirming medical care but also all research and education grants and Medicare and Medicaid funding from organizations that provide gender-affirming medical care.

II. BACKGROUND AND QUALIFICATIONS

8. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

9. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.

10. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

11. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of individuals with gender dysphoria, particularly minors. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's Fetal Care Center's Oversight Committee, which provides the Center recommendations on the use of innovative treatments and experimental interventions.

12. As an academic pediatric hospitalist, I practice and teach evidence-based medicine, including the development and use of clinical practice guidelines. As a bioethicist, I help patients, parents, and healthcare providers address ethical dilemmas and resolve ethical conflicts. This involves analyzing the evidence and reasons supporting different treatment options. I also assist my institution to develop ethically sound policies and procedures.

13. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP Committee on Bioethics from 2005 to 2011. I have also served as a member of ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and recently completed my service on its Healthcare Ethics Consultant Certification Commission.

14. I am the author of 44 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 29 commentaries. My peer-reviewed journal articles have been published in high-impact journals, including the *Journal of the American Medical Association* and *Annals of Internal Medicine.* I am also an author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.

15. I am a member of *Pediatrics'* Executive Editorial Board and its Associate Editor for Ethics Rounds. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I am a member of the Program Committee for ASBH's annual meeting and review abstracts for meetings of other professional organizations, including the Pediatric Academic Societies. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities.*

16. I have previously testified at deposition and/or in court in *Boe v. Marshall*, United States District Court, Middle District of Alabama, No. 2:22-cv-00184-LCB; *Brandt v. Rutledge*, United States District Court, Eastern District of Arkansas, No. 4:21-cv-00450-JM; *Dekker v. Weida*, United States District Court, Northern District of Florida, No. 4:22-cv-00325-RH-MAF;

Doe v. Abbott, District Court of Travis County, Texas, No. D-1-GN-22-000977; *Misanin v. Wilson,* United States District Court, Middle District of South Carolina, No. 2:24-cv-4734-RMG; *Moe v. Yost*, Franklin County Court of Common Pleas, Ohio, Case No. 24-cv-H03-2481; *Noe v. Parson,* Circuit Court of Cole County, Missouri, No. 23AC-CC04530; *Van Garderen v. Montana,* Montana Fourth Judicial District Court, Missoula County, No. DV 2023-541; *Voe v. Mansfiled,* United States District Court, Middle District of North Carolina, Case No. 1:19-cv-864-LCB-LPA; and *Zayre-Brown v. North Carolina Department of Public Safety*, United States District Court, Western District of North Carolina, No. 3:22-cv-191-MOC-DCK. The cases in which I have authored reports but have not testified are listed in my CV (**Exhibit A**).

17. I am being compensated at a rate of $400 per hour for preparation of expert declarations and reports, and for deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

III. SEX, GENDER, AND GENDER IDENTITY

18. While sex is an important category, Executive Order 14168 provides an inadequate definition of sex and ignores the importance of gender and gender identity. It defines sex in a circular manner by defining sex as "an individual's immutable biological classification as either male or female" and female/male as "a person belonging, at conception, to the sex that produces the large[/small] reproductive cells."

19. This definition fails to account for individuals who cannot produce any reproductive cells and individuals who can produce both large and small reproductive cells. Some individuals are born without ovaries or testes and therefore are incapable of producing reproductive cells.[1] There are also individuals who are born with both ovarian and testicular

[1] Chen HA, Grimshaw AA, Taylor-Giorlando M, et al. Ovarian absence: A systematic literature review and case series report. *J Ovarian Res*. 2023;16(1):13; Brauner R, Neve M, Allali S, et al. Clinical, biological and genetic analysis of anorchia in 26 boys. *PLoS One*. 2011;6(8):e23292.

tissue—either present in separate or in the same gonad.[2] While the Executive Order suggests that individuals can only be either female and male, the definitions provided would characterize such individuals as neither or both female and male.

20. The Executive Order ignores the primary role that external genitalia play in determining an individual's sex at birth and the role that chromosomes, hormones, and internal and external genitalia play in assigning an individual's sex in some instances. For example, individuals with complete androgen insensitivity are born with testes, which according to the Executive Order, would make them boys. These individuals, however, have a defect in the testosterone receptor and their bodies cannot respond to the testosterone they produce. They have "female" external genitalia and a shortened vagina but no cervix, uterus, fallopian tubes, or ovaries. They are generally assigned female at birth and only come to medical attention due to a swelling in the groin in infancy or childhood or a failure to begin to menstruate in adolescence. Once a diagnosis is made, contrary to the suggestion of the Executive Order, they are generally not reassigned as male based on the presence of testes.[3]

21. Gender and gender identity are important categories that are distinct from and not a replacement for sex. Gender is commonly defined as the behavioral, cultural, or psychological traits typically associated with one sex and gender identity as a person's internal sense of their gender. The fact that gender identity is internal and subjective does not make it meaningless. Many other important experiences, such as emotions and pain, are internal but nonetheless real. At times, an individual's anticipated gender identity is an important factor in assigning their sex at birth.[4]

22. The Order's definition of gender ideology is also erroneous. Individuals who identity as a gender other than their sex assigned at birth and individuals who support their rights

[2] Syryn H, Van De Vijver K, Cools M. Ovotesticular difference of sex development: Genetic background, histological features, and clinical management. *Horm Res Paediatr*. 2023;96(2):180-189.

[3] Hughes IA, Davies JD, Bunch TI, Pasterski V, Mastroyannopoulou K, MacDougall J. Androgen insensitivity syndrome. *Lancet*. 2012;380(9851):1419-1428.

[4] Mieszczak J, Houk CP, Lee PA. Assignment of the sex of rearing in the neonate with a disorder of sex

are not seeking to replace sex with gender identity. An individual who was assigned male at birth, has a prostate, and identifies as female, for example, is recommended to undergo prostate cancer screening just as individuals with prostates who identify as male are.[5] Their goal is also not "to permit men to self-identity as women and gain access to intimate single-sex spaces and activities designed for women." It is to permit all individuals to live fuller and healthier lives. Executive Order therefore mischaracterizes and oversimplifies sex, gender, and gender identity.

23. As an ethicist, I am concerned that Executive Order 14168's characterization of sex and gender identity lead it to draw erroneous ethical conclusions. The Order erroneously states, "Efforts to eradicate the biological reality of sex fundamentally attack women by depriving them of their dignity, safety, and well-being" and fails to acknowledge the ways in which it deprives individuals whose gender identity is inconsistent with their sex assigned about birth of their dignity, safety, and well-being. This need not be a zero-sum game, and efforts should be made to protect all American's dignity, safety, and well-being.

IV. TERMONOLOGY

24. Executive Order 14187 refers to the use of GnRH agonists, sex hormones, and surgery for the treatment of gender dysphoria as "maiming," "sterilizing," and "mutilation." This characterization inappropriately conflates potential side-effects of gender-affirming medical care with its intention and overstates the risks of gender-affirming medical care. The purpose of gender-affirming medical care is generally to make an individual's body and appearance more consistent with the individual's gender identity and therefore reduce an individual's dysphoria and increase an individual's well-being. While gender affirming-medical care can have side effects, they are generally proportionate to the benefits as described below. Performing a mastectomy to treat breast cancer or hysterectomy to treat endometrial cancer would similarly be mischaracterized if described as maiming or surgical mutilation.

development. *Curr Opin Pediatr*. 2009;21(4):541-547.

[5] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S134.

25. Executive Order 14187 uses the terms "child and children" in a potentially misleading manner. It defines these terms as "an individual or individuals under 19 years of age." Childhood is commonly understood to be a shorter stage in human development which includes infancy (up to 1 year of age), toddlerhood (1 to 5 years of age), childhood (3 to 11 years of age), and adolescence (12 to 18 years of age). With respect to the use of GnRH agonists and sex hormones for the treatment of gender dysphoria, neither of these interventions are indicated for individuals until they have begun puberty.[6] They, therefore, are generally used during adolescence rather than childhood. Furthermore, the Order defines children as including individuals who are 18 years of age. In contrast, most states, including Washington State, consider 18-year-olds to be adults.[7] This Order prevents them from accessing medical care to which they would otherwise have access.

26. Executive Order 14187 also refers to "rapid-onset gender dysphoria" and "other identity-based confusion." Neither of these terms is a validated medical diagnosis. For example, neither is contained in the *Diagnostic and Statistical Manual of Mental Disorders*.[8] "Identity-based confusion" is also demeaning to individuals with gender dysphoria suggesting that they are confused. I, therefore, will not use these terms.

V. THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

A. Clinical Practice Guidelines

27. Executive Order 14187 erroneously refers to the evidence for gender-affirming medical care as "junk science" when in fact this evidence is comparable to the evidence for many other types of medical treatments.

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[6] Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94(9):3132-3154.

[7] National Center for Youth Law. Minor consent and confidentiality: A compendium of state and federal laws. August 2024. Accessed February 3, 2025.

[8] American Psychiatric Association. Gender Dysphoria. In: *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed., text rev. American Psychiatric Publishing; 2022.

28. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.[9] One widely used method of grading the quality of the evidence and the strength of recommendations is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.[10]

29. GRADE states, "In the context of making recommendations, the quality ratings reflect the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation."[11] The GRADE system is more nuanced than the Levels of Evidence Pyramid. In addition to study design, GRADE characterizes the quality of evidence based on risk of bias, consistency, and directness. GRADE distinguishes four levels of evidence: "high," "moderate," "low," and "very-low." These levels are relative to one another and "low" does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence, not just "high" or "moderate" quality evidence.[12]

30. With respect to study design, randomized controlled trials generally provide "high" quality evidence.[13] In a randomized controlled trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases

[9] American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877.

[10] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[11] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):403.

[12] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

[13] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

the likelihood that any differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.[14]

31. By comparison, observational studies generally constitute "low" quality evidence.[15] Observational studies include cross-sectional and longitudinal studies. In cross-sectional studies, investigators collect data at a single point in time. A cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found that those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it.[16] In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures.[17] Examples of longitudinal studies include the studies of the associations between gender-affirming medical care and psychological outcomes discussed below.[18]

32. While randomized trials generally provide "high" quality evidence and observational studies "low," the quality of a study or group of studies may be moved up or down based on other considerations such as the risk of bias.[19]

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[14] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022.

[15] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

[16] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.

[17] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022.

[18] See, for example, de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

[19] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

33. The labels "high" and "low" quality evidence can be misleading if the latter is used in the colloquial sense of poor, inadequate, or junk. While randomized controlled trials are described in the medical literature as "high" quality evidence and observational studies as "low" quality evidence, randomized controlled trials may not be feasible or ethical, may have intrinsic methodological limitations, or may be unavailable in some contexts. "High" quality evidence is not required for a treatment to no longer be considered experimental. A particular quality of evidence as specified by the GRADE system does not necessarily entail a particular strength of recommendation; as described below, "low" quality evidence can be sufficient to justify "strong" recommendations.[20]

34. At times, it may be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.[21]

35. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of

[20] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406; Swiglo BA, Murad MH, Schünemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations Assessment, Development, and Evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-673.

[21] Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.[22]

36. The process for assessing the quality of the evidence is separate and distinct from the process for grading the strength of recommendations based on this evidence.[23] When making recommendations, the authors of guidelines consider a variety of factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use.[24] The GRADE system distinguishes "strong" and "weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation.[25] The larger the differences between the desirable and undesirable consequences and the smaller the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation.[26]

37. Recommendations for pediatric care made by professional associations in clinical practice guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context refers to the consensus of experts when studies are not available.

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[22] Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high quality study design. *Pediatrics*. 2008;122(1):52-57.

[23] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

[24] Andrews JC, Schünemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

[25] Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

[26] Andrews JC, Schünemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

38. For example, of the 236 recommendations in the current clinical practice guidelines by the AAP, only 25 (10.6%) are based on Level A evidence (well-designed and conducted randomized controlled trials). Among its 80 "strong" recommendations, 10 (13%) are based on Level X evidence (exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit or harm) and among its 117 "moderate" recommendations, 50 (42.7%) are based on Level C evidence (multiple observational studies with inconsistent findings, single or few observational studies, or observational studies with major limitations).[27]

39. Clinicians cannot tell their patients to come back later after randomized controlled trials have been conducted. Clinicians must make decisions based on the best, currently available evidence, which may be observational studies or expert opinion. The lack of randomized controlled trials and reliance on "low" quality evidence does not mean that there is not reasonable support for a clinical practice guideline recommendation or that a treatment is not medically necessary.

B. Clinical Practice Guidelines for the Treatment of Adolescents with Gender Dysphoria

40. Gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's (APA's) *Diagnostic and Statistical Manual of Mental Disorders*. This diagnosis is defined by "a marked incongruence between one's experienced/expressed gender and their assigned gender, lasting at least 6 months" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."[28]

41. Gender-affirming care for minors is not experimental in the sense of new or novel. The first reference to the use of GnRH analogs for the treatment of gender dysphoria in

[27] Antommaria AHM, Kelleher M, Peterson RJ. Quality of evidence and strength of recommendations in American Academy of Pediatrics' guidelines." *Pediatrics.* In press. The AAP's clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

[28] American Psychiatric Association. Gender Dysphoria. In: *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed., text rev. American Psychiatric Publishing; 2022.

the medical literature was in 1998, over 25 years ago.[29] In the same year, the World Professional Association for Transgender Health (WPATH), then called the Harry Benjamin International Gender Dysphoria Association, included recommendations regarding gender-affirming hormones for adolescents in its Standards of Care (SOC).[30] Providers at Children's Hospital Boston began treating minors with gender-affirming hormones at this time.[31] Prospective observational trials of GnRH analogs began recruiting participants in 2000.[32] In 2007, Boston Children's Hospital established its Gender Management Service which provided treatment with GnRH analogs, in addition to gender-affirming hormones.[33] The Endocrine Society published its first clinical practice guideline for gender-affirming medical care, which recommended treatment with GnRH analogs, in 2009[34] and WPATH added recommendations about GnRH analogs in the 7th edition of its Standards of Care in 2012.[35]

42. The Endocrine Society published its updated clinical practice guideline for the treatment of gender-dysphoric/gender-incongruent persons, including pubertal suppression, sex hormone treatment, and surgery for gender confirmation, in 2017.[36] WPATH's Standards of Care is currently in its 8th version.[37] The treatments outlined in these guidelines are also endorsed

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[29] Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

[30] Levine SB, Brown G, Coleman E, et al. The standards of care for gender identity disorders. *Int J Transgend.* 1998;2(2). Gender identity disorders is the prior terminology for gender dysphoria. This is the 5th edition of the Standards of Care.

[31] Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

[32] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

[33] Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

[34] Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94(9):3132-3154.

[35] Coleman E, Bockting W, Botzer M, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *Int J Transgend,* 2012;13(4):165-232.

[36] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[37] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

by other medical professional associations including the American Academy of Family Physicians,[38] the AAP,[39] the American College of Obstetricians and Gynecologists,[40] the American Medical Association,[41] the APA,[42] the American Psychological Association,[43] and the Pediatric Endocrine Society.[44]

43. Executive Order 14187 asserts without evidence that WPATH lacks scientific integrity and instructs agencies to rescind or amend all policies that rely on WPATH's guidance. Policies that rely on WPATH's guidance may also rely on other sources for their recommendations. Therefore, even if WPATH's guidance were unreliable, and I am not conceding that it is, policies may nonetheless have a sound basis and rescinding them would not be justified.

44. Gender-affirming medical care is also not experimental in the sense of unproven. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are

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[38] American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. December 2023. Accessed February 3, 2025. Available at https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents.

[39] Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4):e20182162.

[40] American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed February 3, 2025. Available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol*. 2021;137(3):e75-e88.

[41] American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed February 3, 2025. Available at https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Madara JL. Letter to Mr. Bill McBride. April 26, 2021. Accessed February 3, 2025. Available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf.

[42] American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed February 3, 2025. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

[43] American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed February 3, 2025, Available at https://www.apa.org/about/policy/transgender.pdf.

[44] Endocrine Society and Pediatric Endocrine Society. Transgender health: Position statement. December 2020. Accessed February 3, 2025. Available at https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position_statement_transgender_health_pes.pdf.

based on "moderate" and 19 (68%) are based on "low" or "very low" quality evidence. The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.[45] Table 1 (Exhibit B). Ungraded Good Practice Statements draw attention to general principles, like shared decision-making, for which direct evidence is unavailable or not systematically apprised.

45. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in the AAP's clinical practice guidelines described above and in other Endocrine Society guidelines for the pediatric population. For example, none of the Endocrine Society's 84 recommendations in its two other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high" quality evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low" quality evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.[46] Table 1 (Exhibit B).

46. With respect to GnRH analogs, the Endocrine Society specifically "suggest[s] that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development."[47] The evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42

[45] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[46] Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

[47] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3880.

to 5.06 years. The study showed statistically significant decreases in behavioral and emotional problems and depressive symptoms, and increases in general functioning.[48]

47. This is the same level of evidence as supports the use of GnRH analogs for the treatment of central precocious puberty. Central precocious puberty is the premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of precocious puberty include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment predicted final height with actual final height. These studies have additional limitations including small sample sizes. This "low" quality evidence nonetheless is sufficient to support the use of GnRH analogs as treatment for central precocious puberty.[49] Executive Order 14187 therefore subjects the use of GnRH analogs to a double standard. There are no randomized clinical trials for the use of GnRH analogs to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.

48. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include Annelou L. C. de Vries and colleagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.[50]

49. As a result of these studies and healthcare providers' subsequent experience,

[48] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

[49] Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-S8.

[50] See de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include

randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of gender-affirming medical care are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that a sufficient number of participants would enroll in randomized controlled trials for them to be informative.[51]

50. Even if such studies could be conducted ethically, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to blind/mask the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if participants were in the intervention or the control arm of the study due to the physical changes in their bodies, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.[52]

51. While Executive Order 14187 directs the Secretary of Health and Human Services to "use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria," it appears to exclude research on gender-affirming medical care. Even if one were to believe that such care was not currently evidence based, which I do not, there is no evidence that it is impossible to be effective and therefore nothing to justify prohibiting any and all research on its use.

Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med.* 2015;12(11):2206-2214 and Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PLoS One.* 2021;16(2):e0243894.

[51] Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

[52] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

VI. OFF-LABEL USE DOES NOT SUPPORT EXECUTIVE ORDER 14187

52. The fact that GnRH analog and gender-affirming hormone treatment are not approved by the US Food and Drug Administration (FDA) for the treatment of gender dysphoria does not support defunding them. Off-label use of FDA-approved medications is legal, common, and often evidence-based. FDA approval is not required for each and every use of a medication. Once the FDA has approved a medication for one indication,[53] thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications.[54] The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest." It further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."[55] There are several reasons why, even if there is substantial evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it. These reasons include that seeking approval may not be economically beneficial for the sponsor.[56]

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[53] According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed February 3, 2025. Available at https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

[54] U.S. Food & Drug Administration. Understanding Unapproved Use of Approved Drugs "Off Label." February 5, 2018. Accessed February 3, 2025. Available at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

[55] Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014;133(3):563-567. Quotations appear on pages 563, 565, and 564 respectively.

[56] Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc*. 2012;87(10):982-990.

53. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed. Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used to treat gastroesophageal reflux.[57] The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.[58]

VII. GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE

A. Principles of Informed Consent

54. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. In order to participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision-maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention. The patient or the patient's proxy must understand and appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.[59]

55. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making

[57] *See* Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193.

[58] Maltz LA, Klugman D, Spaeder MC, Wessel DL. Off-label drug use in a single-center pediatric cardiac intensive care unit. *World J Pediatr Congenit Heart Surg*. 2013;4(3):262-266.

[59] Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.

medical decisions for their minor children based on their assessment of the individual child's best interest. They generally care about their children and best understand their children's unique needs.[60]

56. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear because the provider intends to look even if the child says no. The provider could, however, ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and (iv) express a preference.[61] Adolescents generally possess comparable medical decision-making capacity to adults. Louis A. Weithorn and Susan B. Campbell, for example, found that 14-year-olds performed similarly to adults with respect to their ability to understand and reason about treatment information.[62]

57. Executive Order 14187 falsely suggests that adults are trying to change a child's sex though gender-affirming medical care. This is not something that adults are doing to children. The diagnosis of gender-dysphoria is based on the child or adolescent's own gender

[60] Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

[61] Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics*. 2018;142(Suppl 3):S129-S132.

[62] Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev*. 1982;53(6):1589-1598.

identity, not a gender identity imposed by the adolescent's parent(s). The adolescent patient's assent is also required for these medical interventions.

58. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to treatment, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that the informed consent process for GnRH analogs and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical practice guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent.[63] Lieke J. J. J. Vrouenraets and colleagues found most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding GnRH analogs.[64]

B. Pediatric Gender-Affirming Medical Care's Benefits, Risks, and Alternatives

59. The potential benefits of gender-affirming medical care in minors include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex characteristics consistent with

[63] See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

[64] Vrouenraets LJJJ, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6):e2020049643.

an individual's gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety.[65]

60. As with all medical treatments, gender-affirming medical care entails risks. One of the potential risks is negative effects on fertility, but this risk should not be overstated as it is in Executive Order 14187. GnRH analogs do not, by themselves, permanently impair fertility. Children with central precocious puberty are routinely treated with GnRH analogs and have typical fertility in adulthood.[66] GnRH analogs are also used for fertility preservation in individuals being treated for cancer.[67]

61. While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became pregnant while on or after discontinuing testosterone therapy.[68] Transgender men and women are also capable of producing eggs and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment.[69]

62. Additionally, the clinical practice guidelines discussed above recommend that healthcare providers offer individuals considering gender-affirming medical care methods to potentially preserve their fertility.[70]

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[65] See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc*. 2021;5(4):1-16.

[66] Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol* (Oxf). 2014;80(4):570-576.

[67] Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci*. 2022;23(4):2287.

[68] Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127.

[69] Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril.* 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med*. 2023;4(1):100858.

[70] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

63. The risk of infertility is also not unique to treatment for gender dysphoria. For example, parents and legal guardians consent to the treatment of medical conditions for their minor children, including some nonmalignant rheumatologic disorders and hematologic conditions, which may impair fertility.[71]

64. While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating that those higher rates are caused or exacerbated by gender-affirming medical care.[72] Rather, contributing factors include conflict between one's appearance and identity, stigma, and rejection.[73] As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.

65. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the FDA to not approve a medication, let alone for the President to defund and seek to ends its use. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity all possible side effects.[74]

66. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the potential alternatives including not providing or receiving the treatment. As stated above, prior to the initiation of gender-affirming medical care, many minors with gender dysphoria have significant, unresolved symptoms that treatment improves. Without medical treatment, these symptoms would persist. The assertion that

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[71] Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int J Mol Sci*. 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol*. 2012;26(3):379-390; Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-1477.

[72] Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex.* 2011;58(1):10-51.

[73] Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health*. 2015;15:525.

[74] U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed February 3, 2025. Available at https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

psychotherapy alone is sufficient to treat gender dysphoria in adolescents is only supported by anecdotal evidence.[75]

C. The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

67. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies singling out this medical care for prohibition based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.

68. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions. As described above, parents can choose treatments that have some chance of damaging their children's gonads and impairing their fertility. Individuals with some types of DSDs, such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria.[76] Parents of children with some types of DSDs may even choose to have their children's gonads removed due to the possible elevated risk of malignancy, which causes infertility.[77]

69. As discussed above, the potential benefits of gender-affirming medical care, including improved psychological outcomes, frequently outweigh the potential risks.

D. Potential Regret Does Not Support Executive Order 14187

70. Patients experiencing regret as a result of any medical treatment is profoundly unfortunate and such individuals should be provided support and additional treatment as needed.

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[75] See, for example, Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300.

[76] Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health*. 2019;16(7):1268.

[77] Abacı A, Çatlı G, Berberoğlu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.

Patients expressing regret over having received a certain kind of medical care, gender-affirming or other medical care, however, does not justify ending that medical care.

71. While there are individuals who received gender-affirming medical care as minors who express regret, contrary to Executive Order 14187, the available studies report that rates of regret regarding gender-affirming medical care are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men experienced regret.[78] Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients.[79] Defunding and ending gender-affirming medical care to prevent regret in a small minority of patients would result in harm to the majority of patients who benefit. The potential for regret should nonetheless be disclosed in the informed consent process, and support and services should be provided to individuals who experience regret.

72. The potential for regret is also not unique to gender-affirming medical care. Parents of children who have undergone feminizing genitoplasty and hypospadias repair have experienced regret over their decisions.[80] For example, Rachel S. Fisher and colleagues found that 38% of caregivers of infants with congenital adrenal hyperplasia reported some level of regret about their child's genital surgery.[81] Executive Order 14187 does not, however, seek to restrict or prevent access to these procedures.

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[78] Wiepjes CM, Nota NM, de Blok CJ, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590. This study analyzes all individuals who presented to the clinic, whether they presented as minors or adults. Regret was assessed in individuals who had undergone gender-affirming surgery that included removal of the gonads. This surgery was only performed on adults.

[79] Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsych Open*. 2021;7(6):e184.

[80] Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health*. 2020;56(10):1514-1520.

[81] Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33.

VIII. THE INCREASED PREVALENCE OF GENDER-AFFIRMING CARE DOES NOT SUPPORT EXECUTIVE ORDER 14187

73. The increased number of transgender individuals and those receiving medical treatment does not justify the Executive Order. The causes of these changes are likely to be multifactorial including increased social acceptance of transgender individuals and availability of gender-affirming medical care.[82] Changes in demographics are not unique to gender dysphoria and have been seen in other conditions such as autism spectrum disorder and childhood-onset type 1 diabetes.[83] These changes are a justification for further research on gender-affirming medical care rather than prohibiting these treatments and thereby preventing further research on them.

IX. EXECUTIVE ORDER 14187 UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

74. Executive Order 14187 violates the integrity of the medical profession and coerces medical professionals to violate their integrity and ethical duties. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. This Executive Order intervenes in these processes replacing medical professionals' judgement with the judgment of the President.

75. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers believe that the potential benefits of gender-affirming medical care outweigh the potential risks for a particular patient, preventing them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing federal fundings and potentially being subject to criminal prosecution.

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[82] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590.

[83] Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and characteristics of autism spectrum disorder among children aged 4 years - Early Autism and Developmental Disabilities Monitoring Network, seven sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ*. 2019;68(2):1-19; DIAMOND Project Group. Incidence and trends of childhood type 1 diabetes worldwide 1990-1999. *Diabet Med*. 2006;23(8):857-866.

X. THE FUNDING RESTRICTIONS LACK MEDICAL OR ETHICAL JUSTIFICATION

76. There is no medical or ethical basis for treating gender-affirming medical or surgical care differently from other care covered by federal funds. Gender-affirming medical care is consistent with generally accepted professional medical standards and is not experimental or investigational. It is endorsed by evidence-based clinical practice guidelines that are themselves based on studies published in the peer-reviewed literature demonstrating that it improves individuals' health outcomes.

77. As described above, gender-affirming medical care is not experimental in the sense of new or novel. Gender-affirming medical and surgical care of adults substantially predates that of minors. Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930s. The first documented male to female gender-affirming genital surgery was performed in 1931, and Christine Jorgensen famously underwent gender-affirming surgery in 1952.[84] WPATH developed in original SOC in 1979.[85]

78. As discussed earlier in this report, gender-affirming medical and surgical care is also not experimental in the sense of unproven. It is evidence-based and is supported by clinical practice guidelines developed my medical professional organizations including the Endocrine Society[86] and the WPATH.[87] The evidence base for gender-affirming medical care in adults does include randomized, double-blind, placebo-controlled trials. One trial compared the effect of testosterone combined with a 5alpha-reductase inhibitor or placebo on muscle strength.[88] It is

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[84] Stryker S. Transgender History. 2nd ed. Seal Press; 2017.

[85] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

[86] Hembree, WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoria/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

[87] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

[88] Gava G, Armillotta F, Pillastrini P, et al. A randomized double-blind placebo-controlled pilot trial on the effects of testosterone undecanoate plus dutasteride or placebo on muscle strength, body composition, and metabolic profile in transmen. *J Sex Med.* 2021;18(3):646-655.

important to note that this trial compared one form of gender-affirming hormone treatment to another, rather than comparing gender-affirming hormone treatment to no treatment at all. The evidence base for gender-affirming surgical care is generally observational studies. WPATH SOC-8, for example, cites five prospective observational studies of gender-affirming chest surgery in individuals assigned female at birth and 8 prospective observational studies of gender-affirming vaginoplasty in individuals assigned male at birth.

79. As described above, the use of GnRH analogs, estrogen, and testosterone "off-label" in gender-affirming medical care also does not inherently imply that this use is experimental.

80. The Executive Order does not provide a sound basis for excluding coverage of gender-affirming medical care and treating it differently from other comparable medical interventions. For example, it does not exclude coverage for the use of GnRH analogs to treat central precocious puberty but prohibits coverage for its use to treat gender dysphoria, even though its use to treat both conditions is supported by comparable levels of evidence.

81. Additionally, while the Executive Order would eliminate coverage of chest surgery for the treatment of gender dysphoria, coverage for comparable surgeries, such as those for gynecomastia, is unaffected. Gynecomastia in the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals who sex assigned at birth is male. While surgeries to treat gynecomastia may at times be performed to lessen pain, they are commonly performed to reduce psychosocial distress. Surgery affirms patients' gender identity, that is, to help someone assigned male at birth feel more typically masculine. Risks associated with the procedure include bruising, bleeding, infection, scarring, poor cosmetic outcome, and loss of sensation.[89] There is nothing unique about chest surgery for gender dysphoria that justifies singling this treatment, or other medical or surgical treatments for gender dysphoria, out for non-coverage.

[89] Nordt CA, DiBVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr.* 2008;20(4):375-382.

82. Executive Order 14187 not only seeks to withhold or withdraw funding for gender-affirming medical care but also perniciously pits one group of patients against one another. It threatens to withhold not only finding for gender-affirming medical care but all research and education grants and Medicare and Medicaid funding from organizations that provide gender-affirming medical care.

XI. CONCLUSION

83. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of other medical decisions that adolescents and their parents or guardians have the discretion to make in consultation with their healthcare professionals.

84. Based on my research and experience as a pediatrician and bioethicist, there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the treat of loss of funding and potential criminal prosecution.

85. There is not a sound medical or ethical basis for excluding gender-affirming medical or surgical care for minors or young adults from coverage by public funds. Such care is evidence-based and is not experimental. Excluding coverage for gender-affirming medical and surgical care is also inconsistent with other coverage decisions.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATED this ____ day of February 2025 at _____, _____.

_____
Armand H. Matheny Antommaria, MD, PhD

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
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(206) 464-7744

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DATED this 5TH day of February 2025 at CINCINNATI, OHIO.

Armand H. Matheny Antommaria, MD, PhD